Remarks

Restriction Requirement

In the Office Action a restriction requirement was made under 35 USC §121 between the following groups of claims:

Group 1 Claims 21-23, 26-28, and 31-37 (in part) are drawn to compounds of formula II with the following substituents:
W is nitrogen;
X, Y and Z are C, or CH;
Either T or U is an optionally substituted lower alkylene;
PHarmceutical compsition, and method of treatmetn using said compounds; classified in classes 514 and 544, various subclasses depending on substituents;

Group 2 Claims 21-23, 26-28, and 31-37 (in part), are drawn to compounds of formula II with the following substituents:
X is nitrogen;
W, Y and Z are C, or CH;
Either T or U is an optionally substituted lower alkylene;
Pharmaceutical composition, and method of treatment using said compounds; classified in classes 514 and 544, various subclasses depending on substituents;

Group 3 Claims 21-23, 26-28, and 31-37 (in part), are drawn to compounds of formula II with the following substituents:
Y is nitrogen;
X, W and Z are C, or CH;
Either T or U is an optionally substituted lower alkylene;
Pharmaceutical composition, and methods of treatment using said compounds; classified in classes 514 and 544, various subclasses depending on substituents;

Group 4 Claims 21-23, 26-28, and 31-37 (in part), are drawn to compounds of formula II with the following substituents:
Z is nitrogen;
X, Y and W are C, or CH;
Either T or U is an optionally substituted lower alkylene;
Pharmaceutical composition, and method of treatment using said compounds; classified in classes 514 and 544, various subclasses depending on substituents;

Group 5 Claims 21-23, 26-28, and 31-37 (in part), are drawn to compounds of formula II with the following substituents:
W and X are nitrogen atoms;
Y and Z are C, or CH;
Either T or U is an optionally substituted lower alkylene;
Pharmaceutical composition, and method of treatment using said compounds; classified in classes 514 and 544, various subclasses depending on substituents;

Group 6 Claims 21-23, 26-28, and 31-37 (in part), are drawn to compounds of formula II with the following substituents:
W and X are C, or CH;
Y and Z are nitrogen atoms;
Either T or U is an optionally substituted lower alkylene;
Pharmaceutical composition, and method of treatment using said compounds; classified in classes 514 and 544, various subclasses depending on substituents;

Group 7 Claims 21-23, 26-28, and 31-37 (in part), are drawn to compounds of formula II with the following substituents:
W and Y are nitrogen atoms;
X and Z are C, or CH;
Either T or U is an optionally substituted lower alkylene;

Pharmaceutical composition, and method of treatment using said compounds; classified in classes 514 and 544, various subclasses depending on substituents;

Group 8 Claims 21-23, 26-28, and 31-37 (in part), are drawn to compounds of formula II with the following substituents:
W and Z are nitrogen atoms;
Y and X are C, or CH;
Either T or U is an optionally substituted lower alkylene;
Pharmaceutical composition, and method of treatment using said compounds; classified in classes 514 and 544, various subclasses depending on substituents;

Group 9 Claims 21-23, 26-28, and 31-37 (in part), are drawn to compounds of formula II with the following substituents:
W and Z are C, or CH;
Y and Z are nitrogen atoms;
Either T or U is an optionally substituted lower alkylene;
Pharmaceutical composition, and method of treatment using said compounds; classified in classes 514 and 544, various subclasses depending on substituents;

Group 10 Claims 21-23, 26-28, and 31-37 (in part), are drawn to compounds of formula II with the following substituents:
One of W, X, Y and Z is oxygen (O) while the rest is C, or CH;
Either T or U is an optionally substituted lower alkylene;
Pharmaceutical composition, and method of treatment using said compounds; classified in classes 514 and 544, various subclasses depending on substituents;

Group 11 Claims 21-23, 26-28, and 31-37 (in part), are drawn to compounds of formula II with the following substituents:
One of W, X, Y and Z is sulfur (S) while the rest is C, or CH;
Either T or U is an optionally substituted lower alkylene;

Pharmaceutical composition, and method of treatment using said compounds; classified in classes 514 and 544, various subclasses depending on substituents;

Group 12 Claims 21-23, 26-28, and 31-37 (in part), are drawn to compounds of formula II with the following substituents:
One of W, X, Y and Z is oxygen (O) while the rest is nitrogen (N), C, or CH;
Either T or U is an optionally substituted lower alkylene;
Pharmaceutical composition, and method of treatment using said compounds; classified in classes 514 and 544, various subclasses depending on substituents. Further restriction and/or election of the species will be required if this group is elected;

Group 13 Claims 21-23, 26-28, and 31-37 (in part), are drawn to compounds of formula II with the following substituents:
One of W, X, Y and Z is sulfur (S) while the rest is nitrogen (N), C, or CH;
Either T or U is an optionally substituted lower alkylene;
Pharmaceutical composition, and method of treatment using said compounds; classified in classes 514 and 544, various subclasses depending on substituents. Further restriction and/or election of the species will be required if this group is elected;

Group 14 Claims 21-23, 26-28, and 31-37 (in part), are drawn to compounds of formula II (that are not in the above groups, e.g., T and U are both optionally substituted lower alkylene), pharmaceutical composition, and methods of treatment using said compounds, classified in classes 514 and 544, various subclasses depending on substituents. Further restriction and/or election of the species will be required if this group is elected;

Applicant provisionally elects, with traverse, the subject matter of Group 14. The right to pursue non-elected subject matter in one or more divisional applications is expressly reserved.

At a minimum, the groups should be rewritten to exclude group identification based on the assignment of T and U. The group -TC(R^6)($R^{6'}$)U- can be, for example, a single carbon chain or it can be a single carbon with optionally substituted lower alkylene units on either side. Certainly searching for compounds with an optionally substituted alkylene group in place of an optionally substituted single carbon chain can not cause a serious burden for the Examiner.

Applicant believes that formula II as defined in claim 21 presents a single core structure and the compounds of this formula exhibit common utility. All the groups should therefore be rejoined and examined as originally presented by applicants.

MPEP §803 mandates two criteria for a proper restriction requirement:

> "(A) The ***inventions must be independent*** (see MPEP §802.01, §806.04, §808.01) or distinct as claimed (see MPEP §806.05 - §806.05(i)); **and**
>
> (B) There must be a ***serious burden*** on the examiner if restriction is required (see MPEP §803.02, §806.04(a)-§806.04(i), §808.01(a), and §808.02)." (Emphasis added.)

Applicant submits the present restriction requirement is improper. Each of the pending claims recites a Markush compound genus. Fragmentation of a Markush compound genus through the use of a restriction requirement is improper because it is inconsistent with the applicable case law and ***contrary to the express directions given by the Patent Office's stated guidelines for restriction of Markush groups as set forth in MPEP §803.02.***

Specifically, in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978), the court articulated the general proposition that:

> [A]n applicant has a right to have *each* claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. ***If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits.*** The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the ***subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.*** *Id.* at 331. (Emphasis added).

The distinction between a rejection of a Markush group and restriction requirement is emphasized in a recent opinion from the Federal Circuit in *In re Watkinson,* 900 F.2d 230, 14 USPQ2d 1407 (Fed Cir. 1990) at page 1409:

> Under *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334, it is *never* proper for an examiner to reject a Markush claim under 35 U.S.C. § 121. *Id.* Section 121 simply does not authorize such a rejection.***[W]ith regard to section 121, ***the rejection of a Markush claim is different from a restriction requirement between different claims***. (Emphasis added)

In view of the case law, the Patent Office has set forth the following general policy regarding restriction of Markush-type claims in MPEP §803.02:

> Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334, ***it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention.*** *In re Harnish,* 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).(emphasis added)

In the present case, the Examiner's use of a "restriction requirement" to force Applicant to limit the genus to one of the "inventions" within the scope of the Markush group when the compounds share a common utility and have a common nucleus, is clearly improper in view of the applicable case law and the stated policy of the Patent Office. In determining the propriety of a Markush grouping each compound must be considered as a whole and should not be broken down into elements or other components. While the Patent Office is allowed to reject a Markush claim based on the judicially created doctrine of improper Markush group based on lack of unity of invention, such a rejection would not be proper in the present case because the claimed compounds all share a substantial structural feature which is disclosed as being essential to at least one disclosed utility (See, *In re Harnish, supra* at 305; and *Ex parte Hozumi*, *supra* at 1060.). Specifically, the claimed compounds all have the similar core structure of bicyclic-pyrimidinone. In addition all of the compounds within the genus share the common utility of inhibiting KSP and of treating diseases associated with KSP, such as disorders associated with cellular proliferation.

While the Office Action states that the compounds are "separated based on the bicyclic core" and this is "not be fragmenting a Markush Group." Applicant strongly objects. This restriction requirement has improperly carved 14 different groups from

Applicant's single Claim 20, based on the definitions for W, X, Y, Z and T and U. This restriction definitely breaks up Applicant's defined groups.

Because the Office Action has improperly required Applicant to limit the genus to one of the "inventions" within the scope of a proper Markush grouping of a single claim, Applicant submits the Restriction Requirement is improper and should therefore be withdrawn.

Conclusion

For the reasons set forth above, examination and allowance of the claims of this application are earnestly solicited.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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